

The listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Previously presented) A spinal nucleus implant for replacement of at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrate to restore function of said spinal disc and related vertebral joint, and implantable into the cavity created by said removal of nucleus pulposus tissue, which comprises:

A swellable, biomimetic plastic, having a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said biomimetic plastic having an inherent shape in which it has a relaxed polymer network in a state of full hydration, having an insertion shape in which it is at least partially dehydrated to a xerogel state and formable into a compacted mode for maximum efficiency of surgical insertion, and capable of anisotropic expansion due to partial rehydration in situ into an indwelling shape that substantially conforms to the size and shape of said cavity and is capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state, said anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and suppressed minimal swelling or swelling in horizontal planes.

2. (Original) The spinal nucleus implant of claim 1 wherein said implant is anisotropically deformable in its said indwelling shape having preferred deformability in a vertical plane and suppressed deformability in horizontal planes under compression in the vertical plane.

3. (Original) The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic is at least partially hydrated in its insertion xerogel state.
4. (Original) The spinal nucleus implant of claim 1 wherein said swellable, biomimetic plastic has been formed in a physiologically safe form by being plasticized with a non-toxic liquid in its insertion xerogel state.
5. (Previously presented) The spinal nucleus implant of claim 4 wherein said non-toxic liquid is present at a concentration less than 50% by weight of the plasticized anisotropically swellable, biomimetic plastic.
6. (Original) The spinal nucleus implant according to claim 3 wherein said non-toxic liquid is selected from the group consisting of glycerol, glycerol monoacetate, glycerol diacetate, glycerylformal, dimethyl sulfoxide, water and mixtures thereof.
7. (Original) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic is a dehydrated anisotropically swellable plastic wherein both said hydrophobic phase and said hydrophilic phase each have hydrophobic and hydrophilic aspects and said hydrophobic phase is a less hydrophilic phase having higher content of hydrophobic groups and said hydrophilic phase is a less hydrophobic phase having higher content of hydrophilic groups, relative to one another.
8. (Original) The spinal nucleus implant according to claim 7 wherein said anisotropically swellable, biomimetic plastic comprises non-degradable polymer with a carbon-carbon backbone.
9. (Original) The spinal nucleus implant according to claim 7 wherein said less hydrophilic phase is a crystalline phase containing nitrile groups.

10. (Original) The spinal nucleus implant according to claim 7 wherein said hydrophilic phase has hydrophilic groups which are selected from a group consisting of hydroxyl, carboxyl, carboxylate, amide, N-substituted amide, amidine and N-substituted amidine.
11. (Previously presented) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has water content more than 70% by weight in said state of full hydration by deionized water.
12. (Previously presented) The spinal nucleus implant according to claim 11 wherein said swellable, biomimetic plastic has water content more than 95% by weight in said state of full hydration.
13. (Original) The spinal nucleus implant according to claim 1 wherein said more hydrophilic phase is substantially discrete hydrophilic domains dispersed in a substantially continuous less hydrophilic domain.
14. (Original) The spinal nucleus implant according to claim 1 wherein both the hydrophilic phase and the hydrophobic phase are substantially continuous hydrophilic domains and hydrophobic domains forming an interpenetrating network.
15. (Original) The spinal nucleus implant according to claim 1 wherein said hydrophobic phase contains crystalline polymer phase detectable by x-ray diffraction.
16. (Original) The spinal nucleus implant according to claim 7 wherein said more hydrophobic phase is substantially discrete crystalline domains dispersed in a substantially continuous more hydrophilic domain.
17. (Original) The spinal nucleus implant according to claim 1 wherein said swellable, biomimetic plastic has hydrophilic lubricious surface.

18. (Original) The spinal nucleus implant according to claim 17 wherein said surface is formed in a gradiented manner with increasing carboxylic groups from the center of said implant towards its outer surface.

19. (Original) The spinal nucleus implant according to claim 1 wherein said implantable device has at least the two following structural components:

a) an inner core from said swellable plastic; and,

b) an outer jacket that is surrounding said core and made from said swellable plastic which is, in its fully hydrated state, less swellable than said inner core.

20. (Original) The spinal nucleus implant according to claim 1 including at least one reinforcing element from a substantially non-swellable material embedded in said swellable, biomimetic plastic.

21. (Previously presented) The spinal nucleus implant according to claim 19 and further including at least one reinforcing element from a substantially non-swellable material embedded in said swellable, biomimetic plastic wherein said at least one reinforcing element is located between said jacket and said core.

22. (Original) The spinal nucleus implant according to claim 20 wherein said at least one reinforcing element is made from an implantable material selected from the group consisting of metal, metal alloys, carbon, ceramics, polymer and combinations thereof.

23. (Original) The spinal nucleus implant according to claim 22 wherein said polymer is selected from a group consisting of acrylic polymer, methacrylic polymer, polyester, polyurethane, polyurea, polyolefin, halogenated polyolefin, polysaccharide, vinylic polymer, polyphosphazene and polysiloxane.

24. (Original) The spinal nucleus implant according to claim 19 wherein said inner core is adherent to and connected to said outer jacket.

25. (Original) The spinal nucleus implant according to claim 20 wherein said reinforcing element is more deformable in axial direction than in lateral direction under axial stress.

26. (Original) The spinal nucleus implant according to claim 20 wherein said reinforcing element has a general shape selected from the group consisting of helix, ring, ellipsoid, cylinder and bellows.

27. (Original) A surgical implant procedure for replacing at least a portion of nucleus pulposus tissue removed from a spinal disc of a living vertebrae to restore function of said spinal disc and related vertebral joint, which comprises:

a) creating a spinal nucleus implant in the form of an anisotropically swellable, biomimetic xerogel plastic, having a two phase structure with a hydrophobic phase having high crystallinity and low water content and with hydrophilic phase having low crystallinity and high water content, said xerogel plastic being capable of anisotropic expansion by rehydration into an inherent shape in which it has a relaxed polymer network in a state of full hydration, and being capable of osmotic movement of liquid therethrough in response to external pressure change to thereby increase and decrease liquid content in its hydrated state said anisotropically swellable biomimetic plastic having preferred swelling in a vertical plane and minimal swelling or suppressed swelling in horizontal planes;

b) surgically removing at least a portion of nucleus pulposus tissue from a spinal disc of a living vertebrae to create a cavity; and,

c) implanting said spinal nucleus implant into said nucleus pulposus cavity in an at least partially hydrated state.

28. (Original) The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated state, has volume substantially larger than volume of said cavity vacated by the removal of nucleus pulposus tissue.

29. (Original) The surgical implant procedure according to claim 27 wherein said spinal nucleus implant, in said fully hydrated state, has a cross-section area substantially equivalent to the cross-section area of said cavity vacated by the removal of nucleus pulposus tissue, and height substantially larger than the height of said cavity, the "height" being the dimension substantial parallel with the spinal axis and "cross-section area" being the area lateral to the spinal axis.

30. (Original) The surgical implant procedure according to claim 27 wherein said xerogel plastic swells in situ substantially more in the direction of the spinal axis than in lateral direction.

31. (Original) The surgical implant procedure according to claim 27 wherein said xerogel plastic is implanted in an anisotropically dehydrated state in which its volume is less than 50% of the volume of said cavity vacated by the removal of nucleus pulposus tissue.

32. (Original) The surgical implant procedure according to claim 31 wherein said xerogel plastic in its anisotropically dehydrated state has the shape optimized for insertion into the cavity through a small incision in the annulus fibrosus, said shape being an approximate shape of a cylindrical body.

33. (Original) The surgical implant procedure according to claim 31 wherein said anisotropically dehydrated state is achieved by anisotropical deformation of said xerogel.

34. (Original) The surgical implant procedure according to claim 33 wherein said anisotropical deformation is achieved by heating the xerogel above its glass transition temperature, exposing it to deforming stress in a selected direction, and cooling it down under its glass transition temperature while still exposed to said deforming stress.

35. (Original) The surgical implant procedure according to claim 33 wherein said anisotropic deformation is achieved by forming said xerogel by drying the hydrated swellable plastic under a restraining stress, preventing shrinking of xerogel in one or more selected directions.

36. (Original) The surgical implant procedure according to claim 35 wherein said restraining stress is an external stress caused by applying pressure in axial direction during the dehydration process.

37. (Original) The surgical implant procedure according to claim 35 wherein said restraining stress is created by the presence of internally embedded structure preventing the shrinking in the direction lateral to the axis.

38. (Original) The surgical implant procedure according to claim 27 wherein said hydrated implant is under axial stress substantially more deformable in axial direction than in lateral direction.

39. (Currently amended) A spinal disc implant which comprises an implant member dimensioned for positioning in a cavity defined between adjacent vertebrae, ~~the implant member defining a longitudinal axis and a length extending along the longitudinal axis~~ the cavity defining a first height, the implant member comprising a swellable plastic, whereby upon at least partial hydration of the implant member, the implant member undergoes anisotropic expansion and has a capacity to swell to a second height ~~length along the longitudinal axis~~ which is greater than the first height ~~space between the adjacent vertebrae~~.

40. (Currently amended) A spinal disc implant according to claim 39 wherein the cavity defined ~~space~~ between the adjacent vertebrae is the disc space.

41. (Currently amended) A spinal disc implant according to claim 39 wherein the first height and the second height are measured along a vertical axis and the implant member further defines a horizontal axis ~~transverse axis~~ and a width ~~length~~ extending along the horizontal axis, ~~transverse axis~~ wherein the swelling length capacity to swell to a second height along the

~~longitudinal axis~~ is greater than the relative swelling capacity of the ~~width along the transverse axis~~ length by at least 25%.

42. (Currently amended) A spinal disc implant according to claim [[41]] 50 wherein the relative swelling capacity ~~of the width~~ of the implant member defines a cross-section[[al]] area which is substantially equivalent to the cross-section[[al]] area of [[a]] the cavity which has been vacated by removal of nucleus pulposis tissue of a spinal disc.

43. (Currently amended) A spinal disc implant according to claim [[39]] 42 further comprising a reinforcing member which assists in limiting the increase in cross-section area ~~width~~ of the implant member ~~along the transverse axis~~.

44. (Previously presented) A spinal disc implant according to claim 43 wherein the reinforcing member is in a form selected from the group consisting of knitted structure, metal spring and helically wound fiber.

45. (Previously presented) A spinal disc implant according to claim 39 wherein the swellable plastic is a hydrogel.

46. (Previously presented) A spinal disc implant according to claim 39 wherein the implant member has a water content of more than 70% by weight.

47. (Previously presented) A spinal disc implant according to claim 39 wherein the implant member is in the form of a xerogel which is dimensioned and configured for insertion through a small incision in an annulus fibrosus.

48. (Previously presented) A spinal disc implant according to claim 41 wherein the volume of the implant member fully swelled in body fluid at body temperature is at least 5% larger than the volume of the cavity into which the implant is implanted.

49. (Currently amended) A spinal disc implant according to claim 41 wherein the implant is capable of assuming three configurations:

(i) an inherent configuration assumed upon full hydration of the implant, the inherent configuration having a cross-section[[al]] area ~~transverse axis width~~ which is substantially equivalent to the cross-section[[al]] ~~width~~ area of [[a]] the cavity, wherein the cavity is formed ~~vacated~~ by removal of nucleus pulposis tissue of a spinal disc[[,]] ; and the inherent configuration defining the second height ~~a height extending upon the longitudinal axis which is greater than the height of said cavity;~~

(ii) an insertion configuration assumed upon at least partial dehydration of the implant which has a smaller volume than the inherent configuration, the insertion configuration dimensioned and configured to facilitate insertion through a small incision in an annulus fibrosus; and

(iii) an indwelling configuration assumed upon insertion of the implant into the cavity vacated by removal of nucleus pulposis tissue of a spinal disc, the indwelling configuration having a ~~transverse axis width~~ cross section area which is substantially equivalent to the cross-section[[al]] area ~~width~~ of the inherent configuration, and a ~~longitudinal axis length~~ height which is less than ~~that~~ the height of the inherent configuration and which is determined by and which corresponds to the height of the said cavity ~~vacated by removal of nucleus pulposis tissue~~ whereby positive swelling pressure is generated by the implant along the longitudinal axis ~~between the adjacent vertebrae~~ to increase vertebral separation.

50. (New) A spinal disc implant according to claim 41 wherein the implant further defines a transverse axis to the vertical axis and perpendicular to the horizontal axis, the horizontal axis and transverse axis defining a plane which is transverse to the vertical axis, the implant having a width which is measured along the transverse axis, wherein the implant has a capacity to expand the width along the transverse axis which is at least 25% greater than the expansion of length measured along the horizontal axis.

51. (New) A spinal disc implant according to claim 50 wherein the length of the implant does not expand along the horizontal axis.